

Rejections under 35 U.S.C. §112, first paragraph

Claims 55 and 56 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Additionally, the Office Action alleges that the broadening in claims 55 and 56 represents new matter. Applicants respectfully disagree.

The written description requirement of §112, first paragraph, is met so long as the invention is described in the specification as broadly as it is claimed. The written description requirement ensures that, as of the filing date, the inventor conveyed with reasonable clarity to those of skill in the art that he was in possession of the subject matter of the claims. *Vas-Cath Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, 1117 (Fed. Cir. 1991).

Support for claim 55 is set forth throughout the application as originally filed, particularly at page 12, lines 16-22. Although the Office Action interprets this section of the application as being directed “to the design of the disinfection to affect only undesired bacteria leaving others unaffected” (Office Action mailed December 31, 2001, at page 2), Applicants respectfully submit that the Office Action fails to take into account the rest of the specification, which states, *inter alia*, that “solutions of PNAs can be used to disinfect objects that have been contaminated with a **particular** bacteria” (page 12, lines 17-19; emphasis added). This disclosure provides direct support for the subject matter of claim 55. One skilled in the art, having read the present application, in particular page 12, line 16-22, would readily appreciate that the inventors had possession of the claimed invention, a method of killing or inhibiting growth of bacteria comprising contacting said bacteria with a peptide nucleic acid and additionally identifying the bacteria to be killed or inhibited.

Support for claim 56 is also set forth throughout the application as originally filed, in particular at page 22, lines 17-35. Although the Office Action alleges that claim 56 lacks written support because the written support on page 22, lines 17-35, is directed to only a cell growth assay on agar media and not directed to other examination procedures.

Applicants note that one of skill in the art, having read the present application, would readily be able to examine the killing or inhibiting of the growth of bacteria subsequent to contacting the bacteria with PNAs. For example, Example 7, (page 22) describes treating *E. coli* with PNAs and growing the bacteria on agar media to determine if the bacteria are killed or inhibited. One skilled in the art, having read the present application, in particular page 22, line 17-35, would readily appreciate that the inventors had possession of the claimed method of killing or inhibiting growth of bacteria comprising contacting said bacteria with a peptide nucleic acid where the killing of the bacteria or the inhibiting of the bacteria's growth is examined after contacting the bacteria with the PNA.

One skilled in the art would also know how to use the claimed invention; *i.e.*, how to examine the bacteria after contact with PNAs. It is well known in the art how to examine bacteria, and how to determine whether the bacteria have been killed or their growth has been inhibited. The Office alleges that visual examination and immunoassays, examples of examining the effect of PNAs on target bacteria, show that claim 56 is not adequately enabled. Applicants disagree. Using the examples cited by the Office, a skilled artisan, employing only routine laboratory experimentation would be able to use the claimed invention and would readily agree that Applicants were in possession of the full scope of the claimed invention at the time of filing. Therefore, claim 56 is fully supported by the disclosure and the specification does convey that the Applicants had possession of the claimed invention at the time the application was filed.

Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 55 and 56 under 35 U.S.C. § 112, first paragraph.

Statutory Double Patenting

Claims 43 and 44 were rejected under 35 USC 101 as allegedly claiming the same invention as that of claims 12 and 13 of US Patent No. 6,300,318. Claims 43 and 44 have been cancelled, obviating this rejection.

Obviousness-type Double Patenting

Claims 23-30 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-6 and 12 of U.S. Patent 6,300,318. Applicants respectfully disagree.

Claims 24, 29, and 30 have been canceled; obviating this rejection to the extent it applies to claims 24, 29, and 30.

The Office Action states that "although the conflicting claims are not identical, they are not patentably distinct from each other because common embodiments of antibiotic *in vitro* bacterial killing are present in both sets of claims" (Office Action, page 4). However, the possibility that claims 23 and 25-28 of the present application share some embodiments of "antibiotic *in vitro* killing" with claims 1-6 and 12 of U.S. Patent 6,300,318 is irrelevant to an obviousness-type double patenting analysis.

The doctrine prohibiting double patenting was created to prevent the extension of patent exclusivity beyond the term of a patent at the expense of the public. Preliminarily, the Examiner is reminded that only the disclosure in claims 1-6 and 12 of U.S. Patent 6,300,318 may be considered for a double patenting rejection. "When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may **not** be used as prior art." (MPEP § 804; emphasis added).

To support a conclusion that the claimed combination is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed combination or the Examiner must present a convincing line of reasoning as to why the skilled artisan would have found the claimed invention obvious in light of the teachings of the references. Further, the Examiner is prohibited from basing an obviousness rejection on hindsight reconstruction by including knowledge "gleaned only from applicants disclosure . . ." *In re McLaughlin*, 170 USPQ 209, 212 (CCPA 1971).

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. The Examiner has failed to provide any motivation to modify the cited reference so as to render the present claims obvious. The Federal Circuit has recently affirmed the requirement for motivation to combine references, stating that:

virtually all [inventions] are combinations of old elements. Therefore, an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed [**10] elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention . . .

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and **with no knowledge of the claimed invention**, would select the elements from the cited prior art references for combination in the manner claimed . . .

To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.

Yamanouchi Pharm. Co. v. Danbury Pharm, Inc., 231 F.3d 1339 (Fed. Cir. 2000); 56 U.S.P.Q.2D 1641, 1645, *citing In re Rouffet*, 149 F.3d 1350, 1357-58, 47 USPQ2d 1453, 1457-8 (Fed. Cir. 1998) (emphasis supplied).

The rejection of claims 23 and 25-28 under the judicially created doctrine of obviousness-type double patenting should be withdrawn. The Examiner has provided no motivation as to why one skilled in the art would modify the disclosure of claims 1-6 and 12 of U.S. Patent No. 6,300,318. The Examiner has provided no reasonable expectation of success that such a modification would work. In addition, the elements of the claimed invention are not taught in claims 1-6 and 12 of U.S. Patent No. 6,300,318. Claim 25 of the present application requires that the peptide nucleic acid be complementary in an anti-parallel orientation to a region of messenger RNA of the bacteria. Claims 1-6 and 12 of U.S. Patent No. 6,300,318 have no such limitation. Furthermore, the claims in U.S. Patent No. 6,300,318 do not set forth any peptide nucleic acid length as is claimed in the present invention (See claims 27 and 28).

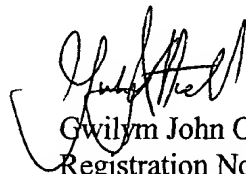
Applicants respectfully request the reconsideration and withdrawal of the rejection of claims 23 and 25-28 under the judicially created doctrine of obviousness-type double patenting.

Notwithstanding the foregoing, in order to advance the prosecution of this application, Applicants may file a terminal disclaimer over U.S. Patent 6,300,318 in the event that allowable subject matter is indicated in the present application.

Attached hereto is a marked-up version of the changes made to the application by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

The foregoing represents a *bona fide* attempt to advance the present application to allowance. Applicants respectfully invite the Examiner to contact the undersigned at (215) 564-8338 to discuss any issues unresolved by this response. A Notice of Allowance is earnestly solicited.

Respectfully submitted,



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Attachments:

"Version with markings to show changes made"

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims

Please cancel claims 24, 29, 30, 43, and 44 without prejudice.